

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Robert G. Pergolizzi et al.

Serial No. 08/479,995

Group Art Unit: 1809

Prior Group Art Unit 1807

Filed: June 7, 1995

Examiner: Ardin H. Marschel, Ph.D.

Title: ANALYTE DETECTION UTILIZING POLYNUCLEOTIDE SEQUENCES, COMPOSITION, PROCESS AND KIT

AS
P#14
8/13/97

INFORMATION DISCLOSURE STATEMENT

HON. COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

This Information Disclosure Statement is filed in accordance with 37 C.F.R. §§1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior ☐ Divisional or ☐ Continuation-in-Part application under 37 C.F.R. §1.60, U.S. Serial No. _____, filed _____.
4. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
 - ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.
 - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application.
 - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.

Enz-11(C2)(D1)(C2)

CERTIFICATE	
Express Mail Label No.	EN449423875
Deposit Date	JULY 25, 1997
I hereby certify that this paper and the attachments thereon are being deposited with the United States Patent and Trademark Office, Express Mail Post Office to be received under 37 CFR 1.10 on the date indicated above and addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231	
<i>Mc</i>	JULY 25 97
Date	

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Serial No.: 08/479,995
Filed: June 7, 1995
Page 2 (Information Disclosure Statement
Under 37 C.F.R. §§1.56 & 1.97-1.98 - July 25, 1997)

5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☒ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
- ☐ A check in the amount of \$200.00 is enclosed in payment of the fee.
- ☒ Charge the fee to Deposit Account No. 05-1135, Order No. ENZ-11(C2)(D1)(C2). A DUPLICATE COPY OF THIS SHEET IS ATTACHED.
7. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
 - b. the attached petition requesting consideration of this Information Disclosure Statement; and
 - c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.
8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:
- a. ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
 - b. ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.
 - c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.

Enz-11(C2)(D1)(C2)

Robert G. Pergolizzi, et. al.
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Under 37 C.F.R. §§1.56 & 1.97-1.98 - July 25, 1997)

9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

10. ☐ A check in the amount of \$130.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).

☒ Charge the fee under 37 C.F.R. §1.17(i)(1) to Deposit Account No. 05-1135. Order No.: Enz-11(C2)(D1)(C2). A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

Dated: July 25, 1997

By: 

RONALD C. FEDUS
Registration No. 32,567
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Enz-11(C2)(D1)(C2)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Robert G. Pergolizzi et al)	
Serial No.	08/479,995)	Group Art Unit: 1809
Filed:	June 7, 1995)	Former Group Art Unit 1807
Title:	ANALYTE DETECTION UTILIZING)	Examiner: Ardin H. Marschel, Ph.D.
	POLYNUCLEOTIDE SEQUENCES.)	
	COMPOSITION, PROCESS AND KIT)	

527 Madison Avenue, 9th Floor
New York, New York 10022
July 25, 1997

FILED BY EXPRESS MAIL

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

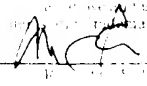
**INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. §§1.56 & 1.97-1.98**

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.97-1.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following thirty-six (36) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

1. Chard, T., An Introduction to Radioimmunoassay and Related Techniques, North Holland Publishing Company, Amsterdam, NY Oxford, 1978 [Exhibit 1]^{1,2}
2. Falkow et al., U.S. Patent No. 4,358,535 issued 11/9/82 [Exhibit 2]^{1,2,3}
3. Wahl et al., U.S. Patent No. 4,302,204 issued 11/24/81 [Exhibit 3]^{1,2,3,4}

Enz-11(C2)(D1)(C2)

EXPRESS MAIL CERTIFICATE	
Express Mail Label No.	EM449423875
Deposit Date	JULY 25, 1997
I hereby certify that this paper and the attachments are being deposited with the United States Express Mail Post Office to be delivered by service under 37 C.F.R. 1.10 on the date of mailing and are addressed to the Commissioner of Patents and Trademarks, Washington, DC 20231	
	JULY 25 97
Date	

4. Heimer, U.S. Patent No. 3,755,086 issued 8/28/73 [Exhibit 4]^{1,2,3}
5. Schuurs et al., Clinica Chimica Acta 81:1-40 (1977) [Exhibit 5]^{1,2,3}
6. Bauman et al., Chromosoma 84:1-18 (1981) [Exhibit 6]^{1,2,3}
7. Manning et al., Biochemistry 16:1364-1370 (1977) [Exhibit 7]^{1,2,3}
8. Broker et al., Nucleic Acids Research 5:363-384 (1978) [Exhibit 8]^{1,2,3}
9. Sodja, Nucleic Acids Research 5:385-401 (1978) [Exhibit 9]^{1,2,3}
10. Shapiro et al., Biochemistry 5:2799:2807 (1966) [Exhibit 10]^{1,2}
11. Litt, Biochemistry 8:3249-3253 (1969) [Exhibit 11]^{1,2}
12. Politz et al., Biochemistry 20:372-378 (1981) [Exhibit 12]^{1,2}
13. Van Wezenbeek, Gene 11:129 (1980) [Exhibit 13]^{1,2}
14. Ward et al., U.S. Patent Application Serial No. 255,223 filed 4/17/81, which is now issued on 12/8/87 as U.S. Patent No. 4,711,955 [Exhibit 14]^{1,2}
15. Engelhardt et al., U.S. Patent Application Serial No. 391,440 filed 6/23/82, which is now issued as U.S. Patent Nos. 5,241,060 on 8/31/93 and 5,260,433 on 11/9/93 [Exhibits 15A and 15B respectively]^{1,2}
16. Tom et al, U.S. Patent No. 4,366,241 issued 12/28/82[Exhibit 16]⁴
17. Rounds et al., U.S. Patent No. 3,798,131 issued 3/19/74 [Exhibit 17]³
18. Heller et al., European Patent Application Publication No. EP 0 070 685 A2 (1/26/83), now issued as European Patent No. EP 0 070 685 B1 on 10/16/85 [Exhibits 18A and 18B]¹

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19. Heller et al., European Patent Application Publication No. 0 070,687 A2 (1/26/83) now issued as European Patent No. EP 0 070 687 B1 on 10/16/85 [Exhibits 19A and 19B]³
20. Kourilsky et al., UK Patent Application Publication No. GB 2,019,408A published 10/31/79, and now issued as UK Patent No. 2 019 408B on 10/31/79 [Exhibit 20]³
21. Ranki et al., PCT Patent Application Publication No. WO 83/01459 published (4/28/83) [Exhibit 21]^{3,11}
22. "M13, A Rapid DNA Cloning and Sequencing System," Bethesda Research Laboratories, Inc. brochure (undated) [Exhibit 22]³
23. Bauman et al., Experimental Cell Research 128:485-499 (1980) [Exhibit 23]³
24. Tereba et al., Proc. Natl. Acad. Sci. (USA) 76:6486-90 (1979) [Exhibit 24]³
25. Ranki et al., U.S. Patent No. 4,486,539 issued 12/4/84 [Exhibit 25]^{2,4,5}
26. Messing, Methods in Enzymology 101:20-78 (1983) [Exhibit 26]⁶
27. Paa et al., U.S. Patent No. 4,556,643 issued 12/3/85 [Exhibit 27]⁷
28. Drlica, Understanding DNA and Gene Cloning, John Wiley & Sons, Inc., NY (1984), page 21 [Exhibit 28]⁸
29. Kourilsky et al., U.S. Patent No. 4,581,333 issued 4/8/86 [Exhibit 29]^{2,4,9}
30. Symons, Nucleic Acid Probes, CRC Press, Inc., Boca Raton, FLA, 1989, pages 130-131 and 36-38 [Exhibit 30]¹⁰
31. Keller et al., DNA Probes, Stockton Press, New York, NY 1989, pages 198-201 [Exhibit 31]¹⁰

32. Piper et al., Nucleic Acid Probes: A Primer for Pathologists, ASCP Press, Chicago, Illinois 1989, pages 49-50 [Exhibit 32]¹⁰
33. Fisher, Z. Physiol. Chem 60:696-78 (1909) [Exhibit 33]¹
34. Ranki et al., Current Topics in Microbiol. Immunology, 104:3097-318 (1989) [Exhibit 34]¹¹
35. Ranki et al., Gene 21:77-85 (1983) [Exhibit 35]¹¹ and
36. Ranki et al., European Patent Application Publication No. 0 079 139 A [Exhibit 36]¹¹
37. PCT/FI 82/00038 [Exhibit 37]¹¹

Of the thirty-six (36) above-submitted documents, thirty (30) documents (Exhibits 1-30) were considered in connection with prior applications by examiners other than the present Examiner, and six (6) documents have not yet been considered in connection with either the instant or prior applications (Exhibits 31-36). A total of seven (7) documents were cited by an opponent (Tm Technologies, Inc.) in an opposition lodged against Applicants' corresponding European Patent No. 0 128 332 B1. Of those six references, namely, (1): Malcolm et al., EP 0 124,221 A1 (11/7/84); (2): Dunn et al., Cell 12:23-26 (Sept. 1977); (3) Dunn et al., Methods in Enzymology, Vol. 65, Part I, Nucleic Acids, pp 468-479 (Grossman, Edu.), Academic Press, NY 1980); (4) Ranki et al., Curr. Top. Microbiol. Immunol. 104:3097:318 (1983); (5): Ranki et al., Gene 21:77-85 (1983); (6): European Patent Application Publication No. EPO 079 139A; and (7) PCT/FI82/00038 (WO 83/01459)), four (4) references, (1) through (3) and (7) supra, were cited and/or considered in connection with prior applications. Thus, three (3) references, (4) through (6) supra, are being submitted herewith (Exhibits 34-36).

A completed Form PTO-1449 listing the above-submitted documents is also attached hereto as Exhibit 37.

For the Examiner's convenience, a listing of all the references cited and/or considered in connection with the instant and/or prior applications, including the thirty-six (36) documents being submitted herewith, is attached hereto as Exhibit 38. Copies of the references previously considered are not being submitted with this Information Disclosure Statement. Applicants' attorney will provide the Examiner with any previously considered reference or references at his request.

In the March 10, 1997 Office Action (page 10), the Examiner indicated that references made of record in prior parent applications were made of record as having been considered in the instant application. The Examiner further indicated that none of the PTO Form 1449s or 892s from the prior parent applications are in the instant file and that Applicants are required to supply copies of the executed forms. In compliance with the Examiner's request, Applicants are also submitting, attached hereto as Exhibit 39, copies of all executed PTO Form 1449s and 892s from prior parent applications.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the instant application.

The above citation of references is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant references, nor are these documents necessarily a complete listing of all references known to Applicants or their attorney. It is simply a voluntary citation of references made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own search.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither suggested nor disclosed by the documents submitted herein. Thus, their invention is patentably distinct thereover. Moreover, Applicants do not believe, and do not submit, by the citation of these documents, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

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Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.

The fee under 37 C.F.R. §1.17(p) for filing this Information Disclosure Statement is \$230.00. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,



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Registration No. 32,567
Attorney for Applicants

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Tel. (212) 583-0100

FOOTNOTES

1. Cited in the specification of U.S. Patent Application Serial Nos.: 06/491,929 filed 5/5/83; 06/922,757 filed 10/24/86; 07/607,787 filed 10/26/90; 07/805,274 filed 12/10/91; 08/032,769 filed 3/16/93; and 08/342,667 filed 11/21/94, and in the instant application 08/479,995, filed June 7, 1995.
2. Cited in an IDS filed 12/17/93 in connection with U.S. Patent Application Serial No. 08/032,769 filed 3/16/93.
3. Cited in a June 3, 1985 Amendment in Response To Restriction Requirement and Information Disclosure Statement Under 37 C.F.R. §§1.56 and 1.97 in connection with U.S. Patent Application Serial No. 06/491,929, filed May 5, 1983 and considered by an examiner on 8/21/85 on Form PTO-1449.
4. Cited in a 10/13/92 Office Action in connection with U.S. Patent Application Serial No. 07/805,274, filed 12/10/91 (and appearing on Form PTO-892 dated 9/30/92).
5. Cited in a 9/9/85 Office Action in connection with U.S. Patent Application Serial No. 06/491,929, filed 5/5/83 (and appearing on Form PTO-892 dated 8/22/85).
6. Considered on PTO Form 1449 dated 8/21/85 in connection with U.S. Patent Application Serial No. 06/491,929, filed 5/5/83.
7. Cited in a 3/24/86 Office Action in connection with U.S. Patent Application Serial No. 06/491,929, filed 5/5/83 (and appearing on Form PTO-892 dated 3/24/86).
8. Cited in a 12/29/88 Office Action in connection with U.S. Patent Application Serial No. 06/922,757, filed 10/24/86 (and appearing on form PTO-892 dated 12/16/88).
9. Cited in a 7/10/91 Office Action in connection with U.S. Patent Application Serial No. 07/607,787, filed 10/26/90.
10. Cited in a 12/10/91 Amendment Under 37 C.F.R. §1.115 in connection with U.S. Patent Application Serial No. 07/607,787, filed 10/26/90.
11. Cited by an opponent (Tm Technologies, Inc.) in opposition lodged against Applicants' corresponding European Patent No. O 128 332 B1.

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